Bill Number: SB 1 Chaptered Chapter 11

Filed with Secretary of State May 20, 1997 Introduced by Senator Burton

December 2, 1996

An act to add Section 2248 to the Business and Professions Code, relating to health, and declaring the urgency thereof, to take effect immediately.

The People of the State of California do enact as follows: Section 1. Section 2248 is added to the Business and Professions Code, to read:

2248. This section shall be known as, and may be cited as, the Grant H. Kenyon Prostate Cancer Detection Act.

(a) If a physician and surgeon, during a physical examination, examines a patient's prostate gland, the physician and surgeon shall provide information to the patient about the availability of appropriate diagnostic procedures. including, but not limited to, the prostate antigen (PSA) test, if any of the following conditions are present:

- (1) The patient is over 50 years of age.
- (2) The patient manifests clinical symptomatology.
- (3) The patient is at an increased risk of prostate
- (4) The provision of the information to the patient is medically necessary, in the opinion of the physician and surgeon.
- (b) Violation of subdivision (a) constitutes unprofessional conduct and is not subject to Section 2314.

Section 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the Constitution and shall go into immediate effect. The facts constituting the necessity are:

Prostate cancer is currently a leading cause of cancer death in males in this country. In order to save as many people's lives from this deadly disease as soon as possible through public awareness of the availability of early detection procedures, it is necessary that this act take effect immediately.

responding to important medical issues by incorporating elements of clinical practice guidelines in effect at that time into legal requirements. It is important for physicians to understand these legal requirements while they seek to apply an evolving body of knowledge to the individual patient in their care.

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REFERENCES

American Urological Association, Inc®. Early Detection of Prostate Cancer. Board of Directors, September 1997 (revised)

American Cancer Society. Cancer Facts & Figures 1998: Special Section: Prostate Cancer. 1998. Available: http://www.cancer.org/statistics/cff98/special.html. 8/10/98

National Cancer Institute. PDQ® Detection & Prevention—Health Professionals. 1998. Available: http://cancernet.nci.nih.gov/clinpdq/screening/Screening _for_prostate_cancer_Physician.html#1.8/10/98

American College of Physicians guidelines. Ann Intern Med 1997; 126(6):

The Urethral Sling and Stress Urinary **Incontinence**

STRESS URINARY INCONTINENCE affects between 15-60% of women, and has a tremendous impact on a woman's quality of life. Incontinence is either urgency or stress in nature. Urgency incontinence and mild SUI can be successfully managed in general with behavioral or anticholinergic treatment. Moderate to severe SUI is best managed by operative intervention. The following epitome discusses the role of urethral slings in the management of SUI.

Stress urinary incontinence is defined as the involuntary loss of urine related to increases in abdominal pressure resulting from activities such as laughing, coughing, lifting, and positional changes. Two factors are important to the development of stress urinary incontinence: urethral hypermobility and/or intrinsic sphincteric deficiency. Both factors commonly coexist and vary in their relative contribution in women with stress urinary incontinence. Hypermobility is the rotational descent of the proximal urethra and bladder neck into the vagina when there are increases in intra-abdominal pressure. Intrinsic sphincteric deficiency refers to a deficiency in urethral sphincter function, and is generally unrelated to urethral support. All operative procedures for stress urinary incontinence address either or both of these factors. The selection of a surgical procedure for stress urinary incontinence therefore depends on the relative contributions of urethral hypermobility and intrinsic sphincteric deficiency. Stress urinary incontinence related primarily to bladder neck hypermobility can commonly be corrected with routine bladder neck suspensions or urethral slings. If, however, urethral sphincteric deficiency is the primary cause of stress urinary incontinence, urethral bulking agents, artificial urinary sphincters, and sling procedures are appropriate. Of the treatment modalities mentioned, the urethral sling is the only procedure that addresses both the hypermobile urethra and intrinsic sphincteric deficiency. In addition, there has been a relatively recent realization that intrinsic sphincteric deficiency plays a more prominent role in stress urinary incontinence than previously believed. These two factors have led to an increase in the popularity of the urethral sling procedure.

In 1910, Goebell introduced the concept of a urethral sling by using reflected pyramidalis muscle as a bolster for the urethra. This is analogous to a leather seat supporting a child on a swing. Since then, several modifications using different autologous (e.g. rectus fascia, fascia lata, vaginal wall) as well as synthetic (e.g. mersilene, Gortex, Marlex) materials have been used. The utility of synthetic materials, however, is limited because of complications including bladder erosion, infection, and fistula formation. There has been a recent interest in the use of homologous tissue for urethral slings, and the initial results appear promising.

Approaches to the urethral sling can be classified as transabdominal, transvaginal, and a combination of both. There is no compelling evidence that one approach is

superior to the others. The type of operation is best determined by surgeon preference and experience. Regardless of approach, the principles are the same: a broad base support directly under the urethra, which is placed with only minimal tension.

The American Urologic Association Female Stress Urinary Incontinence Clinical Guidelines Panel conducted a comprehensive review and in-depth analysis of published outcome data pertaining to different surgical procedures for urinary incontinence. This panel concluded that urethral slings, along with retropubic bladder neck suspensions, are the most efficacious procedures for long-term success in the treatment of urinary incontinence secondary to urethral hypermobility. They report a greater than 85% probability of improvement of urinary incontinence at 48 months or longer with the use of urethral slings. Although outcome literature is sparse for patients with intrinsic sphincteric deficiency treated with slings, it was the panel's opinion that this procedure is also an effective type of treatment for intrinsic sphincteric deficiency patients. Possible complications of sling procedures include prolonged urinary retention, urgency and urgency-related incontinence. The risk of postoperative urgency ranges from 7-46% and can be quite debilitating to the patient. Urinary urgency is best managed with behavioral training (fluid moderation, timed voiding, pelvic floor exercises) or anticholinergic medications. In general, if urgency is present preoperatively, there is a significant risk that these symptoms will persist postoperatively. The risk of permanent retention, however, is low at less than 5% and can be managed with clean intermittent catheterization or urethrolysis.

The urethral sling addresses urethral hypermobility and may address intrinsic sphincteric deficiency. This versatility, along with excellent cure rates and low complication rates, have led many to apply this operation to most types of stress urinary incontinence to those patients who have opted for surgical intervention.

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REFERENCES

Leach GE, Dmochowski RR, Appell RA, Blaivas JG, Hadley HR, Luber KM, Mostwin JL, O'Donnell PD, Roehrborn CG. Female Stress Urinary Incontinence Clinical Guidelines Panel summary report on surgical management of female stress urinary incontinence. J Urol 1997; 158:875–880

Baldwin DD, Hadley HR. Stress urinary incontinence. In: Urinary incontinence. p. 190-197. O'Donnell PD, editor. Mosby-Year Book, Inc; 1997. St. Louis, Missouri

Peyronie's Disease: A Difficult Sexual Dysfunction Problem

PEYRONIE'S DISEASE IS a physically and psychologically devastating problem that affects up to 2% of men. Those affected are primarily between the ages of forty and sixty. Peyronie's disease is manifested by fibrous, inelastic scar tissue involving the tunica albuginea of the penis, the fibrous jacket surrounding the spongy, vascu-

lar tissue of the corpora cavernosa, which expands during the development of an erection. The inelastic scar is palpable in the flaccid penis, but a penile deformity such as bending, narrowing, hinging, and/or shortening can be visible when the penis becomes erect. Painful erections may occur particularly in the early phase of the disease. All of these changes can result in difficulty with vaginal penetration and may be further exacerbated by concomitant disorders such as diabetes, hypertension, elevated serum lipids, or a smoking history that could cause decreased arterial inflow or venous leakage.

The disease received its name in the 1740s from Francois de la Peyronie, who was the first surgeon to King Louis XV. Despite all treatment options available since then, it still remains a therapeutic dilemma. Most commonly, the characteristic Peyronie's plaque is found on the dorsum of the penis causing an upward curvature during erection. However, other plaque locations can occur, resulting in various penile deformities. To understand how the erection deformity occurs, imagine the effect of placing a piece of tape on a child's balloon. As the balloon expands, it will curve around the inelastic segment caused by the tape.

The cause of Peyronie's disease remains an enigma. There have been many theories, including sexually transmitted, inflammatory, or autoimmune. The mechanical injury theory suggests that trauma to the erect penis activates the disease process. More current proposals suggest that Peyronie's disease may, in fact, be a wound healing disorder, much like a keloid or hypertrophic scar. It has been noted in patients with Peyronie's disease that elastin, the protein which allows for normal tunical expansion, is decreased or abnormal in the outer jacket. Therefore, pressure on the erect penis during intercourse can stretch the tunical fibers, and, due to the decreased tolerance to stress, a delamination or fracture injury typically involving the septal and inner circular fibers of the tunica may occur. Following injury, the release of cytokines activate fibroblast proliferation and collagen, the primary extracellular matrix component of a Peyronie's plaque, is produced. Disregulation in the genetic code could cause a loss of balance between scar formation and remodeling. The result is the deposition of an exuberant scar which does not remodel properly.

Although Peyronie's disease may resolve spontaneously, this appears to be uncommon (around 15%). Treatment options include conservative therapy, which is the treatment of choice for many patients (30%). This would include observation of the man who has minor curvature (e.g. <30°), which does not interfere with his ability to have sexual relations, and neither he nor his partner experience pain during intercourse. This patient should be reassured that this is a disease that will not degenerate into malignancy. Oral therapies have also been used, although there is no clear, reliable, efficient choice. The most common oral medications currently used are vitamin E, Potaba (potassium aminobenzoate) and colchicine. Drugs injected directly into the plaque have also been used, including steroids, verapamil, and collagenase. The use of steroids has fallen out